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KENT H. CHENG, ESQ.
Cohen, Pontani, LIEBERMAN & Pavane
551 fifth Avenue, Suite 1210
New York, NY 10176

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 05/23/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/543,489

Applicant(s)

CALIAS ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72,74 and 75 is/are pending in the application.
- 4a) Of the above claim(s) 3,5-8 and 22-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,9-21,72,74 and 75 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

Final Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 1-75 are pending in the present application. Claims 3, 5-8, and 22-71 stand withdrawn as being drawn to a nonelected invention. Claims 1, 2, 4 and 9-21 will be examined to the extent they read on the elected species (i.e., composition comprising EDU).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 4 and 9-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite compounds wherein "G₂ is a group having a neutral or a net charge". The present specification lacks definition of G₂ as a group having a neutral

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charge. According to the present specification, G₂ is a group having a net charge that is preferably a net positive charge (see page 2, lines 33-34; page 7, lines 20-21 and pages 9-11).

Claim 1 also recites "a prodrug derivative thereof" and claims 2 and 72-75 recite EDU or "a salt thereof". The present specification lacks recitation of the cited phrases and description of said phrases.

In summary, the presently claimed invention is not described in the present specification in full, clear, concise and exact terms to convey to the skilled artisan in the art that applicant had possession of the claimed invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 12 recites the limitation "wherein the sustained release delivery system is a microencapsulated product" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

The instant claim is dependent on claim 1 which does not recite a sustained release delivery system. It is assumed applicant intended the instant claim to be dependent on claim 11. Correction is requested.

Claim Rejections - 35 USC § 102

7. The rejection of claim 73 under 35 USC 102(b) over Ito et al. ('151) is made moot by the cancellation of the instant claim.

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8. The rejection of claims 2 and 74 under 35 USC 102(b) over Ito et al. ('151) is withdrawn.

9. The rejection of claims 72 and 75 under 35 USC 102(b) over Ito et al. ('151) is maintained and claims 1, 9 and 10 are rejected under 35 USC 102(b) over Ito et al. ('151).

Applicant argues water in the EDU solution of the Ito is not a pharmaceutically sterile liquid carrier. Applicant's argument was considered but not persuasive for the following reason.

According to the present specification sterile liquid carrier includes water (see page 26, lines 23-26). The reference teaches EDU in water and, thus, is encompassed by the instant claims.

For this reason and those given in previous Office Actions, the rejection of claims 72 and 75 under 35 USC 102(b) over Ito et al. ('151) is maintained and claims 1, 9 and 10 are rejected under 35 USC 102(b) over Ito et al. ('151).

10. Claims 1, 9, 10, 72 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Beuvery et al.

Beuvery et al. teach a composition comprising EDU (see the entire article, especially page 120, iv. EDU; page 122, Toxic potentials of EDU and of EDU; page 126, 1st paragraph). The compositions taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 2, 4, 9-21, 72, 74 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beuvery et al.

Beuvery et al. teach a composition comprising EDU (see the entire article, especially page 120, iv. EDU; page 122, Toxic potentials of EDU and of EDU; page 126, 1st paragraph).

The instant claims differ from the reference by encompassing compositions not exemplified by the reference. For example, the instant claims include solids, aerosols and sustained released compositions. However, formation of different preparations is well within the level of skill of the ordinary artisan. Therefore, formulation of solid, aerosol and sustained release compositions of EDU for use as taught by Beuvery would be within the level of skill of the ordinary artisan. The motivation would be based on the desire to test the toxicity of the compound via different routes of administration.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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Barbara Padio

Barbara P. Badio, Ph.D.

Primary Examiner

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BB

May 22, 2003